



NDA 10-155/S-021

Sanofi-Synthelabo, Inc.
Attention: Thomas Conroy
Regulatory Manager
90 Park Avenue
New York, NY 10016

Dear Mr. Conroy:

Please refer to your supplemental new drug application dated August 27, 2002, received August 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mytelase (ambenonium chloride) Capsules.

We acknowledge receipt of your submission dated September 5, 2002.

This supplemental new drug application provides for the addition of a Geriatric subsection to the PRECAUTIONS section of labeling. The specific language added is as follows:

Geriatric Use: "Clinical studies of MYTELASE did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy."

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted September 5, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teresa Wheelous, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.

Director

Division of Neuropharmacological Drug Products

Office of Drug Evaluation I

Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Russell Katz

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